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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,373	09/22/2003	Hidehiro Yamazaki	033025-006	5015

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,373	YAMAZAKI, HIDEHIRO	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *5-8 and 10-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,9 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2/3/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-15 are pending in this application.

Applicant's election with traverse of the invention of Group VI (claim 9) in the response of 2/27/2006 is acknowledged. Applicant argues that "there is no serious burden on the Examiner to examine all of the claims in the present application particularly since the searches are co-extensive." Applicant asserts that "the restriction requirement is in error and should be withdrawn." The Examiner does not agree. Applicant does not appreciate the serious burden an application such as this places on the Examiner. Take a close look at claims 1 and 9 and ask how Group VI has to be searched:

Claim 1 (Currently Amended) A method for controlling water and electrolyte balance and acid-base equilibrium in a patient in need of such treatment, comprising administering continuously to the patient a preparation solution containing 130 to 145 mEq/L of sodium ion, 2 to 5 mEq/L of potassium ion, 20 to 35 mEq/L of bicarbonate ion, 90 to 130 mEq/L of chloride ion, 2 to 5 mEq/L of calcium ion, 0.5 to 2.5 mEq/L of magnesium ion, 1 to 7 mEq/L of citrate ion, and 0 to 5g/L of glucose at a rate of 2 to 60mL/kg/hour in an amount sufficient to control water and electrolyte balance and acid-base equilibrium in the patient .

Claim 9 (Currently Amended) A method as claimed in ~~any one of claims 1 to 3 for controlling water and electrolyte balance and acid-base equilibrium of a~~ claim 1, wherein said patient in need of such treatment is a patient ~~under the~~ undergoing an operation ~~and~~ or is a post operative patient.

There are 7 required ingredients at very specific concentration ranges. How does one conduct a search for concentration ranges? If one searches in commercial databases for, say 130-145 mEQ/L sodium by querying that range, a reference that shows 135-140 mEQ/L would be excluded. So concentration ranges are impossible to search efficiently. The Examiner must go through an unduly burdensome search, wherein contents of all potential electrolyte solutions must be reviewed and compared component by component. This is a laborious and time consuming task given the ubiquitous presence of applicant's claimed electrolytes. Hence, restricting between various patient condition or patient types is proper here – doing so reins in the search to a level that is still difficult, but not unduly burdensome. Therefore, applicant's argument is deemed unpersuasive.

However, upon reconsideration, the Examiner will withdraw the restriction requirement with respect to claim 4. In other words, claims 4 and 9 constitute the modified-elected invention, and claims 1-3 and 15 will presently be examined along with claims 4 and 9 *to the extent* that they read on claims 4 and 9, i.e. the elected invention.

Claims 5-8 and 10-14 are withdrawn from further consideration as being directed to non-elected subject matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10-203961.

JP 10-203961[1] discloses treating ketoacidosis, without causing alkalosis, by administering a solution that contains the following electrolytes:

sodium: 120-150 mEq/L;

potassium: 0-10 mEq/L;

chloride : 90-120 mEq/L ;

calcium : 0-5 mEq/L;

magnesium: 0-5 mEq/L;

bicarbonate: 20-35 mEq/L;

citrate: 1-5 mEq/L.

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[1] This is a Japanese language document. For applicant's convenience, a full machine translation and also an English language abstract, HCAPLUS Abstract 1998:498580, is provided

See machine Translation of claim 1 and paragraphs 5, 8-9; see also HCAPLUS Abstract 1998:498580. Correction of acidosis with bicarbonate is generally disclosed (machine translation of paragraphs 2-3). The electrolyte solution set forth above is administered as an infusion[2] at the time of "surgical stress" to provide electrolyte balance (machine translation of paragraph 13). Dose is taught to be suitably adjusted according to a patient's symptoms, age, weight, etc., at 500-8000 ml/per day (id.). Administration rate of 60 ml/kg/hr and higher rates are exemplified (machine translation of paragraph 17).

All of the claimed features in the rejected claims are met. Controlling electrolyte balance is explicitly taught and controlling water balance would necessarily be obtained from the administration of the same exact solution. The patient in JP 10-203961 suffers from ketoacidosis, which is a type of metabolic acidosis, and can include patients under surgical stress. The makeup of the solution in JP 10-203961 compares as follows with applicant's invention:

	JP 10-203961	Applicant's claimed invention
sodium:	120-150 mEq/L	130-145 mEq/L
potassium:	0-10 mEq/L	2-5 mEq/L
chloride :	90-120 mEq/L	90-130 mEq/L
calcium :	0-5 mEq/L	2-5 mEq/L
magnesium:	0-5 mEq/L	0.5-2.5 mEq/L
bicarbonate:	20-35 mEq/L	20-35 mEq/L
citrate:	1-5 mEq/L	1-7 mEq/L.

[2] "[T]ransfusion" in the machine translation, e.g., paragraph 13, which would have been understood by a skilled artisan in this field as an infusion.

It is the Examiner's position that the concentration of the claimed invention would have been immediately envisaged by the skilled artisan in this field from the narrow range of identical components disclosed by JP 10-203961.

Further, continuous administration is necessarily disclosed from the need to control acidosis, as well as the disclosure of 500-8000 ml/per day and 60 ml/kg/hr.

For these reasons, the claims are anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10-203961 in view of Medline abstract 93060291, HCAPLUS abstract 1984:188290 and HCAPLUS abstract 1997:400035.

Teachings of JP 10-203961 have been discussed above and the discussion there is incorporated herein by reference.

Medline abstract 93060291 discloses that hormonal change after surgical stress and anaerobic glucolysis due to tissue ischemia cause acidosis. Postoperative complications also cause acidosis. Acidosis is specifically found in gastrointestinal

surgery. Alkalosis is discussed as a result of bicarbonate production from lactate and citrate supplied by massive infusion and transfusion.

HCAPLUS abstract 1984:188290 discloses that the use of blood gas analytical parameters for monitoring and therapy of patients with acid-base disturbances is known.

HCAPLUS abstract 1997:400035 discloses an apparatus capable of determining CO_2 partial gas pressure and pH from blood gas analysis for clinical diagnosis. The apparatus is "convenient for monitoring acidosis or alkalosis."

Claims 1, 4 and 9 have been rejected as being anticipated over JP 10-203961, so there is no patentable difference between said claims and this reference. The following is an alternative discussion of JP 10-203961 under obviousness analysis, in view of secondary references.

Even if it could be argued that the solution in JP 10-203961 does not match exactly in content, one having ordinary skill in the art would have been motivated to adjust from the narrow range taught by JP 10-203961 the solution makeup and concentration as claimed to control water and electrolyte balance and acid-base equilibrium in patients suffering from metabolic acidosis and surgical or postoperative patient. The motivation for such adjustment would come from monitoring and responding to the patient's blood parameters, which must be done when treating acid imbalance.

As for the claimed feature of 2-60 ml/kg/hour, the Examiner's position is that such infusion speed is already explicitly taught by JP 10-203961. 60 ml/kg/hr is exemplified by JP 10-203961. Additionally, the reference discloses 500-8000 ml/per day, which is to be adjusted according to a patient's symptoms, age, weight, etc. To the ordinary skilled artisan, the claimed 2-60 ml/kg/hour feature would have been obvious from the reference disclosure since determining how much of the infusion to administer or how fast to administer would depend on patient condition and weight, at least. For example, acute cases of acidosis would indicate higher infusion speed because more bicarbonate would be needed to more quickly counteract the greater degree of acidosis. And as the patient stabilizes, the ordinary skilled artisan would have been motivated to adjust the infusion speed lower or demedicate because the acidosis is already under control. Given such level of the ordinary skill in the art, the following sample calculation would have been obvious:

	8000 ml/day (maximum taught by JP 10-203961)	4000 ml/day (1/2 of maximum taught by JP 10-203961
Typical 80 kg male	4.2 ml/kg/hr	2.1 ml/kg/hr
Typical 60 kg female	5.6 ml/kg/hr	2.8 ml/kg/hr

The calculations above are shown merely to establish that applicant's lower range of infusion speed would have been obvious.

The secondary references HCAPLUS abstract 1984:188290 and HCAPLUS abstract 1997:400035 further establish the motivation of the ordinary skilled artisan to adjust the infusion speed or demedication of the solution as discussed above, because said references establish that close monitoring of the patient's blood parameters via blood gas analysis is practiced when treating acidosis. The secondary reference by Medline abstract further establish the motivation of ordinary skilled artisan to treat surgical and postoperative patients with the solution taught by JP 10-203961.

As for the feature of claim 3, which requires adjusting infusion speed to maintain a plasma bicarbonate concentration to be in a range of 22 to 26 mEq/L, it is the Examiner's position that such method step is but a truism for virtually all acidosis treatments since the normal plasma bicarbonate concentration in humans is 24 mEq/L.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

Applicant's IDS is noted. Three foreign language documents with partial English translations are cited. Initials next to the references indicate only that the references were considered to the extent of the partial English translations.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN PAK
PRIMARY EXAMINER
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